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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,844	09/19/2000	Volker Zimmer	RDID0044US	9010

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Jill L Woodburn
The Law Office of Jill L. Woodburn LLC
6633 Old Stonehouse Drive
Newburgh, IN 47630

EXAMINER

PADMANABHAN, KARTIC

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/554,844

Applicant(s)

ZIMMER ET AL.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5,7-10,13 and 15-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,5,7-10,13 and 15-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 371 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification.

Specification

3. **Content of Specification**

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

Or alternatively, Reference to a "Microfiche Appendix": See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.

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- (e) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
 - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (f) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (g) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (h) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (i) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations

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to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

- (j) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).
- (k) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Applicant should include headings in the specification for the relevant sections outlined above.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2-3, 5, 7-10, 13, and 15-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. In claims 1-3, 5, 7-10, and 16-23, applicant should insert "The" as the first word in the claims, so the claims read "The analytical test element..."

7. Claim 2 recites the limitation "the inner surface" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 2 is rejected as vague and indefinite for the recitation of "capable" because it has been held that the recitation that an element is "capable of" performing a function is not a

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positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

9. Claim 7 is rejected as vague and indefinite for the recitation of the detection element that "is formed to act as a filter" because the way in which the detection element is formed to achieve this purpose has not been recited.

10. Claim 8 is rejected as vague and indefinite for the recitation of "capable" because it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

11. Claim 10 is rejected as vague and indefinite for the recitation of "capable" because it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

12. Claim 13 recites the limitation "the determination" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

13. Claim 13 provides for the use of an analytical test element, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 13 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex*

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parte Dunki, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F.

Supp. 131, 149 USPQ 475 (D.D.C. 1966).

14. Claim 15 recites the limitations "the determination" in line 1 of the claim, "the edge" in line 8 of the claim, and "the surfaces" in lines 9-0 of the claim. There is insufficient antecedent basis for these limitations in the claim.

15. Claim 15 is rejected as vague and indefinite for the multiple recitations of "capable" because it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

16. Claim 18 is rejected as vague and indefinite for the recitation of "all necessary reagents" because this terminology does not allow for the metes and bounds of the claim to be adequately identified.

17. Claim 19 recites the limitation "the detection reaction" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

18. Claim 21 recites the limitation "the cover" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

19. Claim 21 is rejected as vague and indefinite for the recitation of "capable" because it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

20. Claim 23 is rejected as vague and indefinite because applicant has recited that the cover is bonded, but has not specified to what the cover is bonded.

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21. Claim 24 recites the limitations "the determination" in line 1 of the claim and "the surfaces" in line 8 of the claim. There is insufficient antecedent basis for these limitations in the claim.

22. Claim 36 is rejected as vague and indefinite for the multiple recitations of "capable" because it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

23. Claim 36 recites the limitation "the presence" in lines 17-18 of the claim. There is insufficient antecedent basis for this limitation in the claim.

24. Claim 36 is also rejected as vague and indefinite for the recitation of drawing conclusions about analyte presence by observing the detection element because applicant has not specified on what basis the conclusions are drawn. Claim 36 appears to be incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are the manner in which some sort of reaction occurs once sample enters the detection element to allow for observation of some result, and the way in which this result is interpreted to determine analyte presence.

Claim Rejections - 35 USC § 102

25. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

26. Claims 13, 15, 18-19, 24, and 36-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Attridge et al. (US Pat. 5,192,502). The reference discloses a device for analyte determination comprising a pair of parallel transparent plates with a capillary cavity therebetween to allow uptake of sample liquid, one of said plates being a light-transmissive waveguide having a reagent appropriate to the assay immobilized on its internal surface. The other plate has a light-absorbing material coated on its external surface.

27. Claims 2-3, 5, 7-10, 13, and 15-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Zimmer et al. (US Pat. 5,814,522). The reference discloses a multilayer analytical element and method for the determination of analyte in a liquid, wherein said element comprises an application zone and detection zone side by side on a stacked complex composed of fleece and a porous membrane, wherein said fleece and porous membrane are in fluid contact via a contact area which permits passage of fluid there through, a portion of said porous membrane being in the detection zone and having a detection reagent which forms a signal upon interaction with analyte. Sample may be applied directly to the sample application zone, but the use of a capillary channel is also compatible with the device of the reference. One possible embodiment of the analytical element is the location of the fleece and membrane on a support foil which has a hole in the area of the test zone containing reagent. A covering foil is attached with a spacer on the fleece side in such a way that there is a capillary gap in the sample application zone. There may be a vent if the channel is only open at the inlet side. The porosity of the membrane acts to filter out certain particles. Analyte presence can be determined visually or by an instrument.

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28. Claims 2, 3, 5, 7, 13, 15, 18-20, 22, 24, and 36-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Vetter et al. (US Pat. 5,851,838). The reference discloses a diagnostic test carrier and method comprising a supporting layer, a detection layer arranged on the supporting layer, said detection layer comprising reagents for the detection of an analyte, an inert layer covering the detection layer and attached to the supporting layer, wherein the inert layer is spaced such that capillary liquid transport may occur. The supporting layer may comprise foil. The detection layer comprises a porous membrane, which inherently filters out certain particles due to its pore size exclusion. Signal is detected in the detection layer when analyte interacts with reagent.

29. Claims 2-3, 5, 7-10, 13, and 15-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Vetter et al. (US Pat. 6,025,203). The reference discloses a diagnostic test carrier and method comprising a supporting layer, a detection layer on the supporting layer, said detection layer having reagents incorporated therein for analyte detection, a network covering the detection layer which is attached to the supporting layer in a manner that allows for capillary transport of liquid. The network may be made of a first and second material, wherein the second material is more hydrophilic than the first. The supporting layer may be made of foil. The detection layer comprises a porous membrane, which inherently filters out certain particles due to its pore size exclusion. The test carrier may also comprise a cover located over the network region which extends beyond the detection layer.

Double Patenting

30. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

31. Claims 2-3, 5, 7-10, 13, and 15-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,592,815. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite analytical test elements and methods of detection comprising similar elements and steps, and one of ordinary skill in the art would recognize that the two sets of claims read on each other.

Conclusion

Claims 2-3, 5, 7-10, 13, and 15-40 are rejected.

Interest: Wenz et al., Crismore et al., and Thym et al. are cited as art of interest for teaching a diagnostic test carrier and methods of detection.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509.

The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

10/01/03